Weisman

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: **03-02**

2. STATE: Oregon

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID) Medical Assistance

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: March 1, 2003

JAN 31 2003

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
1902(a)(30)(A)

7. FEDERAL BUDGET IMPACT:
a. FFY 2003-2004 ($ 984,038)
b. FFY $ -0-

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1-A, page 5-a
Attachment 3.1A, page 5-b (P+I)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1-A, page 5-a
Attachment 3.1A, page 5-b (P+I)

10. SUBJECT OF AMENDMENT:
This transmittal is being submitted to allow collection of supplemental rebates.

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Per Attachment 7.3A

12. SIGNATURE OF STATE AGENCY OFFICIAL: Lynn Read [signature] Jean Thorne [signature]

13. TYPED NAME: Lynn Read Jean I. Thorne

14. TITLE: Acting Administrator, OMAP ~~Acting~~ Director, DHS

15. DATE SUBMITTED: 1-28-03

16. RETURN TO:
Office of Medical Assistance Programs
Department of Human Services
500 Summer Street NE, 3rd Floor, E35
Salem, OR 97301

ATTN: Carole Van Eck

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: JAN 31 2003

18. DATE APPROVED: NOV - 4 2003

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: MAR - 1 2003

20. SIGNATURE OF REGIONAL OFFICIAL: /S/

21. TYPED NAME: Karen S. O'Connor

22. TITLE: Associate Regional Administrator
Division of Medicaid & Children's Health

23. REMARKS:
Pen & Ink change authorized by the State 6/19/03

Oregon (03-02)
Approved: 11/4/03
effective: 03/01/03

LIMITATIONS ON SERVICES (Cont.)

12.a. Prescribed Drugs

Reimbursement is available to covered outpatient drugs of any manufacturer that has entered into and complied with an agreement under Section 1927(a) of Title XIX of the Social Security Act, which are prescribed for a medically accepted indication. Drugs subject to limitations are those outlined under Section 1927(d)(4) of Title XIX of the Social Security Act.

The Department will maintain a list of drugs to be referred to as the Practitioner Managed Prescription Drug List (PDL). The PDL is a listing of prescription drugs that the Department has determined represents the most effective drug(s) at the best possible price for the selected drug classes. The PDL will include other drugs in the class that are Medicaid reimbursable and which the FDA has determined to be safe and effective if the relative cost is less than the benchmark drug(s). When pharmaceutical manufacturers enter into supplemental rebate agreements with DHS that reduces the cost of their drug below that of the benchmark drug for the class, their drug will also be included in the PDL. The PDL is developed with a governor appointed committee, the Health Resource Commission (HRC), in coordination with the Drug Utilization Review Board. The HRC conducts an evidence-based evaluation of selected classes of prescription drugs covered by the Department. The HRC will make drug effectiveness recommendations to the Department.

A practitioner may prescribe any Medicaid reimbursable, FDA approved drug that is not listed on the PDL. If the practitioner in the exercise of professional judgement considers it appropriate for the diagnosis or treatment and is within the practitioner's scope of practice, he/she may prescribe a non-PDL drug by notating such anywhere on the prescription. Regardless of the PDL, prescriptions shall be dispensed in the generic form unless practitioner requests otherwise subject to the regulations outlined in 42 CFR 447.331, ORS 689.515.

The state utilizes The Oregon State University College of Pharmacy for literature research and the state DUR (Drug Utilization Review) Board as the Prior Authorization committee. Criteria used to place drugs on Prior Authorization is based upon safety, efficacy and clinical outcomes as provided by the product labeling of the drug. The prior authorization process provides prescribing physicians, pharmacists, and/or designated representatives the ability to contact the Medicaid PA unit via a toll free telephone or other telecommunication device. Responses are issued within 24 hours of the prior authorization request. Pharmacies are authorized to dispense a 72 hour supply of a prior authorized product in the event of an emergency. The program complies with requirements set forth in Section 1927 (d)(5) of the Social Security Act pertaining to prior authorization programs.

LIMITATIONS ON SERVICES (Cont.)

12.a. Prescribed Drugs

The state is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

CMS is approving a rebate agreement between the state and a drug manufacturer that provides supplemental rebates for drugs provided to the Medicaid program, submitted to CMS on 6/19/2003 and entitled, "State of Oregon, Supplemental Rebate Agreement".

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

12.b. Dentures

Dentures are not covered for adults.
Dentures are covered for children under the EPSDT Program.

12.c. Prosthetic Devices

Prosthetic devices are provided. OMAP Durable Medical Equipment and Medical Supplies Guide describes services provided, prior authorization requirements, and limitations of services and payments.

12.d. Eyeglasses

OMAP Visual Services Guide describes services covered and limitations which apply.

SUPPLEMENTAL REBATE AGREEMENT

This Agreement is between the State of Oregon, acting by and through its Department of Human Services, Office of Medical Assistance Programs, hereafter called Agency, and (name of Manufacturer), hereafter called Manufacturer. Agency's Contract Administrator for this Agreement is _____ 503/___-____. Manufacturer's Contract Administrator for this Agreement is _____ (phone #_____).

RECITALS

WHEREAS, Agency has the authority to enter into agreements with pharmaceutical manufacturers to collect supplemental rebates for the benefit of Agency's Medicaid recipients providing such agreements are approved by the Center for Medicare and Medicaid Services (CMS); and

WHEREAS, Manufacturer is willing to provide supplemental rebates to Agency based on the actual dispensing of Manufacturer Covered Product(s) under the State of Oregon's Medicaid program.

AGREEMENT

NOW THEREFORE, in consideration of the foregoing Recitals and the mutual terms and conditions set forth below, the parties, intending to be legally bound, agree as follows:

1. **DEFINITIONS.** As used herein, the following terms shall have the meanings set forth below. Terms not defined herein that are defined in 42 USC 1396r-8 shall have the meaning of the term used in that statute.

1.0 **"Agency"** shall mean, for purposes of this Agreement, the Oregon Department of Human Services, it officers and employees, and may include in Agency's discretion, a pharmacy benefits manager under contract with Agency.

1.1 **"Agreement"** means this Supplemental Rebate Agreement, including all documents attached or incorporated by reference.

1.2 "**Benchmark Drug**" shall mean the drug for each Plan Drug List class that has been identified by DHS as the benchmark drug in its Practitioner-managed Prescription Drug Plan.

1.3 **"CMS"** shall mean the Center for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration) of the U.S. Department of Health and Human Services, or any successor or renamed agency carrying out the functions and duties heretofore carried out by such office.

1.4 **"CMS Basic Rebate"** shall mean, with respect to the Covered Product, the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Medicaid Drug Rebate Agreement made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. 1396r-8(c)(1) and 42 U.S.C. 1396r-8(c)(3)).

1.5 "**CMS CPI Rebate**" means, with respect to the Covered Products, the quarterly payment by the Manufacturer pursuant to Manufacturer' CMS Medicaid Drug Rebate Agreement, made in accordance with 42 USC 1396r-8(c)(2).

1.6 "**CMS Medicaid Drug Rebate Agreement(s)**" shall mean the agreement(s) in place between Manufacturer and the Secretary of Health and Human Services for CMS Basic Rebates and CMS CPI Rebates, pursuant to Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).

1.7 **"Covered Product(s)"** shall mean any specific pharmaceutical product(s) covered by this Agreement as a supplemental rebate drug, as detailed in Attachment A of this Agreement.

1.8 **"Medicaid Recipient"** shall mean any person enrolled in the State of Oregon's Medicaid Program and eligible to receive prescription drug benefits reimbursed by Agency.

1.9 "**Medicaid Utilization Information**" means the information on the total units of each dosage form and strength of the Manufacturer's Covered Product reimbursed during a quarter under this Agreement. This information is based on claims paid by DHS during a calendar quarter and not drugs that were dispensed during a calendar quarter. The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Covered Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid during the quarter by NDC number.

1.10 **"Net Price"** means the amount(s) agreed upon by the parties to this Agreement in the attached "Supplemental Rebate Formula, Exhibit B." "Net Price" will vary by Covered Product in accordance with Exhibit B.

1.11 **"Pharmacy"** shall mean a facility licensed to dispense legend drugs, and enrolled as a State of Oregon Medicaid provider.

1.12 **"Plan Drug List (PDL)"** shall mean drugs listed in classes of drugs in the PMPDP rule, OAR 410-121-0030, covered by the State of Oregon Medicaid Program.

1.13 "**Practitioner Managed Prescription Drug Plan (PMPDP)**" shall mean the plan that lists PDL drugs in covered classes that can be obtained on the Oregon Medicaid Program without requesting an exception

1.14 **"State Medicaid Program"** shall mean the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid Recipients.

1.15 **"State Supplemental Rebate"** shall mean an amount paid on a calendar quarter basis by Manufacturer to Agency for utilization under Agency's Medicaid program pursuant to this Agreement.

1.16

"State Supplemental Rebate Amount" means, with respect to Covered Product(s), the amount(s) specified in the attached Supplemental Rebate Formula Exhibit B, that the Manufacturer has agreed to reimburse Agency per unit of drug.

1.17 **"Unit"** means a single capsule or smallest issue measure of a Covered Product.

1.18 **"USC"** means the United States Code. All references to this agreement to USC chapters or sections shall include any successor, amended, or replacement statute.

1.19 **"OAR"** means the Oregon Administrative Rules. All references in this Contract to OAR chapters or sections shall include any successor, amended, or replacement regulation.

1.20 "**Quarter**" shall mean, for the period from January 1 through March 31 will be Quarter 1; the period from April 1 through June 30 will be Quarter 2; the period from July 1 through September 30 will be Quarter 3; and the period from October 1 through December 31 shall be Quarter 4.

1.21 "**Day**" shall mean calendar day.

2. AGENCY OBLIGATIONS

2.1 **Plan Drug List.** To be eligible for the Supplemental Rebates specified in Attachment B:

(a) Agency shall place and maintain Covered Product(s) on the PMPDP Plan Drug List, it being agreed that utilization shall be eligible for the State Supplemental Rebate only in quarters in which Covered Product(s) is listed on the PMPDP Plan Drug List; and

(b) Agency shall obtain a fully executed CMS Exemption Letter, attached hereto as Exhibit C and incorporated by this reference, and shall have on file any other required federal approvals.

(c) In the event Agency requires prior authorization of Manufacturer's Covered Product(s) as a part of a product category, Supplemental Rebates shall nevertheless be payable hereunder. If, however, a Covered Product(s) of the Manufacturer shall require prior authorization and not the whole product category on the PDL, Manufacturer shall not be required to provide Agency with Supplemental Rebates for the product.

2.2 **PMPDP Plan Drug List Documentation and Publication.** Agency shall communicate the inclusion of Covered Product(s) on the PMPDP Plan Drug List to State of Oregon Medicaid Program providers through the standard notification process.

2.3 **Utilization Data.** Agency will maintain Medicaid Utilization Information applicable to the Covered Product(s) for use in calculating the State Supplemental Rebate. Agency will provide aggregate Medicaid Utilization Information applicable to Covered Product(s) to Manufacturer on a quarterly basis in connection with the invoicing required under paragraph 2.5.

2.4 **Calculation of State Supplemental Rebate**. In order to be included in the PDL under paragraph 2.1 of this Agreement, the Net Price of Manufacturer's Covered Product(s) to Agency must be less than the Benchmark Drug price for the drug class, after deduction of

the CMS Basic Rebate and CMS CPI Rebate. The amount of reimbursement necessary to bring the Net Price of the Covered Product to the price needed for placement on the PDL shall be the State Supplemental Rebate Amount under this Agreement. The Supplemental Rebate shall be calculated pursuant to the Supplemental Rebate Formula in Exhibit B.

2.5 **Invoicing.** Agency shall calculate and invoice Manufacturer for State Supplemental Rebates separately from CMS Basic or CMS CPI Rebates using the format set forth by CMS (Reconciliation of State Invoice format), consistent with the requirements of paragraphs 2.3 and 2.4. Agency shall submit the State Supplemental Rebate invoice to Manufacturer within sixty (60) days after the end of each calendar quarter in which the Covered Product(s) subject to such State Supplemental Rebate was paid for by Agency. Any amended invoice shall be submitted by Agency within fifteen (15) months after the end of the calendar quarter in which Covered Product(s) was paid for by Agency.

(a) Quarter 1 invoices shall be due by May 30 of the same year;
(b) Quarter 2 invoices will be due by August 29 of that same year;
(c) Quarter 3 invoices will be due by November 29 of that same year;
(d) Quarter 4 invoices will be due by February 29 of the following year.

2.6 Agency shall fully and accurately report the State Supplemental Rebate, including interest, in any applicable cost report to CMS and shall remit the appropriate share of the State Supplemental Rebate payments made under this Agreement to CMS as required under Agency's approved state plan.

2.7

Agency must provide, upon request by the Secretary of Health and Human Services, any information related to this Agreement, including information provided by the Manufacturer as specified in 42 CFR 1001.952(h)(3)(ii), to the extent applicable to this Agreement.

3. MANUFACTURER OBLIGATIONS

3.1 **Continuing CMS Rebate Obligations.** Pursuant to its separate CMS Medicaid Drug Rebate Agreement and CMS CPI Agreement, Manufacturer will calculate and provide CMS rebates to Agency for the Covered Product(s), which includes the CMS Basic Rebate and the CMS CPI Rebate, as appropriate. Manufacturer's obligation for CMS rebates will continue for the duration of the Manufacturer's CMS Agreement.

3.2 **State Supplemental Rebate Payment.** In addition to the CMS Basic Rebate and the CMS CPI Rebate, Manufacturer agrees to pay a Supplemental Rebate to Agency based on the invoice submitted under paragraph 2.5 for each of its Covered Product(s) dispensed to Medicaid Recipients by Pharmacies for each calendar quarter that Covered Product(s) are included in the PMPDP Plan Drug List. Manufacturer 's obligation to pay Agency the Supplemental Rebate shall be in accordance with the formula set forth in Attachment B. The Supplemental Rebate for the quarter will be determined by multiplying the number of units of the Covered Product(s) reimbursed by Agency in the preceding quarter by its Supplemental Rebate Amount. Nothing in this Agreement shall be construed to relieve Manufacturer from its obligation to pay Medicaid Drug Rebates for utilization by State of Oregon Medicaid Recipients.

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3.3 **Payment Timeframe.** Manufacturer shall pay to Agency the State Supplemental Rebate which Agency is entitled in accordance with the formula set forth in Attachment B, within thirty (30) days of Manufacturer's receipt of Agency's rebate invoice pursuant to Section 2.5. Using eight (8) days as reasonable time for reports to reach the manufacturer, payment of the invoiced amounts is due on the following schedule.

(a) Rebate payment for Quarter 1 shall be due by July 7 of that same year;
(b) Rebate payment for Quarter 2 shall be due by October 7 of that same year;
(c) Rebate payment for Quarter 3 shall be due by January 6 of the following year; and
(d) Rebate payment for Quarter 4 shall be due by April 6 of the following year.

3.4 **Interest Payment.** Manufacturer's Supplemental Rebate amount shall include any applicable interest in accordance with Section 1903(d)(5) of the Act. Interest on the Supplemental Rebate begins accruing 38 calendar days from the postmark date of the Agency invoice and interest will continue to accrue until the postmark date of the Manufacturer's payment. For the rebates invoiced under this Agreement, if the date of mailing of a rebate payable under this agreement is 69 days or more from the date of mailing the invoice, the interest rate shall be calculated as required under federal guidelines for rebates under the CMS Basic Rebate.

3.5 **Disputes.** Any dispute about the rebate invoice or any failure to make timely payment in full of the amount due shall initiate a dispute. Timely is defined as 38 days after the postmarked date of the invoice. Disputes shall be addressed using the Dispute Reolution Procedures in OAR 410-121-0580, except that any references in such rule to the Rebate Agreement shall be construed to refer to this Supplemental Rebate Agreement.

3.6 **Over/Underpayment.** If either party discovers an error in the payment of State Supplemental Rebates, it shall notify the other of such error. The parties shall attempt to reconcile all differences through discussion and negotiation; if that attempt fails, the parties will resolve their dispute in accordance with OAR 410-121-0580. Any adjustment shall be credited or recouped, as applicable, from subsequent State Supplemental Rebates payable under this Agreement. In the event that no subsequent State Supplemental Rebates are payable, Agency will refund any such overpayment to Manufacturer within thirty (30) days of the parties' acknowledgement of the overpayment. Manufacturer will remit any underpayment to Agency within thirty (30) days of the parties' acknowledgement of such underpayment.

3.7 **Discretion to Market.** Nothing in this Agreement shall be construed to prohibit Manufacturer from discontinuing production, marketing or distribution of any Covered Product or from transferring or licensing any Covered Product to a third party. It is understood that Manufacturer is liable for the payment of State Supplemental Rebates only for Covered Product(s) (as identified by the 11-digit NDC code) distributed (directly or through the wholesale channel) to medical or pharmacy providers and dispensed to Medicaid Recipients. If Manufacturer elects to discontinue production, marketing or distribution of any Covered Product or to transfer or license any Covered Product to a third party, Manufacturer shall make every reasonable effort to notify Agency prior to such actions.

3.8 Manufacturer shall refrain from doing anything that would impede DHS's ability to meet its obligations under paragraph 2 of this Agreement.